IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ELI LILLY AND COMPANY and THE TRUSTEES OF PRINCETON UNIVERSITY, Plaintiffs, v. TEVA PARENTERAL MEDICINES, INC. and APP PHARMACEUTICALS, LLC, Defendants.	)	C.A. No. 08-335-GMS (Consolidated)

MEMORANDUM

I. INTRODUCTION

In this consolidated patent infringement action, plaintiffs Eli Lilly and Company and The Trustees of Princeton University (collectively, "Eli Lilly") allege that pharmaceutical products proposed by defendants Teva Parenteral Medicines, Inc. ("Teva") and App Pharmaceuticals, LLC ("App") (collectively, "the defendants") infringe the asserted claims of US Patent No. 5,344,932 (the "'932 Patent"). (D.I. 1.) The defendants have asserted the affirmative defense of obviousness-type double patenting, based on their contention that the asserted claims of the '932 Patent are not patentably distinct from claims 11 and 12 of U.S. Patent No. 4,996,206 (the "'206 Patent"), claim 3 of U.S. Patent No. 5,028,608 (the "'608 Patent"), and/or claim 7 of U.S. Patent No. 5,248,775 (the "'775 Patent"). Presently before the court are the plaintiffs' Motion in Limine No. 1 (D.I. 67) and the defendants' Motion in Limine No. 3 (D.I. 71). The issue in both motions is the critical date or dates that the court should use when determining what constitutes "prior art" with respect to the '932 Patent for the purposes of the defendants' obviousness-type

double patenting defense. On October 29, 2010, the court issued an order granting the defendants' motion and denying Eli Lilly's. (*See* D.I. 89.) This memorandum provides the reasoning behind the court's order.

II. DISCUSSION[1]

Eli Lilly concedes that the issue of what types of references constitute prior art is governed by 35 U.S.C. § 102. It argues, however, that § 102 does not resolve for the purposes of an obviousness-type double patenting ("OTDP") analysis the question that it asserts "is relevant here: in light of the prior art ***as of what date***?" (D.I. 83 at 1 (emphasis in original).) This attempt to draw a line between the questions of "what" and "when" is only superficially appealing, however, because the answer to both questions can be found in § 102. Moreover, the questions of "what" and "when" in § 102 cannot easily be compartmentalized, since § 102 does not specify a single rule for "when." Instead, the answer to the question of "when" varies depending on the type of prior art reference at issue. Under § 102(a), the relevant date is the date of invention; under 102(b), it is one year prior to the filing date; and 102(e) and 102(g) are based on interactions between a number of different dates. Adopting Eli Lilly's argument would, in effect, require the court to view some portions of these provisions as controlling while viewing others as irrelevant in the OTDP context. Since one cannot easily disentangle the prior art framework created by § 102, adopting such an approach would be problematic.

If the Federal Circuit wished to carve out such exceptions from § 102, it surely would provide explicit direction rather than allowing exceptions to be created by implication. The court concludes, however, that the Federal Circuit has never indicated that such exceptions have been

[1] The underlying facts of this case are well-known to the parties and need not be discussed for the purposes of this memorandum, which addresses a strictly legal issue.

made either for double-patenting cases in general or for OTDP cases in particular. In its briefs and at oral argument, Eli Lilly cited the Federal Circuit's decision in *Takeda Pharm. Co. v. Doll*, 561 F.3d 1372 (Fed. Cir. 2009) for the proposition that the filing date is the relevant date for conducting the OTDP analysis. Eli Lilly further asserts that in *Amgen, Inc. v. F. Hoffman-La Roche Ltd.*, 580 F.3d 1340 (Fed. Cir. 2009), the Federal Circuit "clarified" *Takeda* by holding that it is the effective filing date rather than the actual filing date that should be used in such cases. (*See* D.I. 67 at 2-3.) The court concludes that *Takeda* and *Amgen* do not stand for the proposition that Eli Lilly asserts. Rather, the court concludes that *Takeda* involved a unique set of facts and that the Federal Circuit's decision in *Amgen* limited *Takeda's* holding to those facts. Certainly, the *Takeda* decision did not announce any major change to the rules governing prior art in the context of OTDP cases.

In the instant case, the disputed claims of both the '932 patent and the allegedly invalidating prior patents cover compositions. In *Takeda*, by contrast, while the earlier patent consisted of composition claims, the patent-in-suit covered a process for making those compositions:

> *Takeda* presented the situation where a patent applicant sought to overcome a double patenting rejection of a process patent over a product patent by presenting post-invention evidence of alternative processes of making the product. . . . Takeda obtained a patent on the product in 1981, and a patent on the process in 1996, both of which claimed priority to [a] 1974 application. . . .[2]

Amgen, 580 F.3d 1354-55 (internal citations omitted). *Amgen* then characterized the holding in *Takeda* as follows:

[2] Like the patents at issue in the instant case, the patents in *Takeda* were filed before June 8, 1995, thus making them subject to the now-displaced patent term regime under which the patent term begins on the issue date rather than the filing date.

> The question on appeal to this court in *Takeda* was whether, when an issued patent claims a product and discloses, but does not claim, a process for making that product, the patentee, when later seeking a patent on the disclosed process, may present evidence of post-invention, alternative processes that produce the patented product, in order to show that the process and product are patentably distinct. The answer was a qualified yes. We concluded that "the relevant time frame for determining whether a product and process are 'patentably distinct' should be at the filing date of the secondary application," which is the later application for the process.

Amgen, 580 F.3d at 1355. In *Amgen*, the Federal Circuit stated that *Takeda* stood for a "limited proposition," and seemed to restrict *Takeda's* holding to its fact. Specifically, the *Amgen* court held that due to § 120's priority rules, "an applicant can only rely on subsequent developments in the art up to the filing date of the 'secondary application' in order to show that alternative processes to make the product render the product and the process for making that product patentably distinct." *Id.* at 1357.

Both parties argue, and the court agrees, that *Takeda* and *Amgen* are somewhat less than clear on the issue of prior art in OTDP cases. Neither decision explicitly implements a prior art framework for OTDP that differs from the framework governing other invalidity issues. On the other hand, neither case explicitly states that the usual prior art rules generally apply in OTDP cases. Consequently, the court concludes that neither case effected a general change in the prior art rules for OTDP cases, especially outside the product/process situation addressed in *Takeda*.

With that in mind, the court researched and examined the case law on prior art in OTDP cases as it existed prior to *Takeda* to see how courts have approached this issue in the past. The court was only able to discover a relatively small number of cases that even examined the issue of using prior art as part of the OTDP analysis.[3] In the relevant cases the court did find,

[3] One reason for this is that the OTDP analysis focuses heavily on the differences between the actual claims

however, there was no indication that prior art in the OTDP context was governed by rules other than those found in § 102. In *In re Longi*, the Federal Circuit, quoting a 1963 opinion issued by the Court of Customs and Patent Appeals, stated that a "fundamental" component of the OTDP doctrine is that:

> The public should . . . be able to act on the assumption that upon the expiration of the patent it will be free to use not only the invention claimed in the patent but also modifications or variants which would have been obvious to those of ordinary skill in the art at the time the invention was made, taking into account the skill of the art and *prior art* other than the invention claimed in the issued patent.

In re Longi, 759 F.2d 887, 892-93 (Fed. Cir. 1985) (quoting *In re Zickendraht*, 319 F.2d 225, 232 (CCPA 1963)) (emphasis added). The *Longi* court did not indicate that the term "prior art" as used in OTDP cases is governed by rules other than those laid out in § 102.[4] Similarly, in the few other opinions the court located that discuss prior art in the OTDP context, the courts did not indicate that the types of prior art that could be considered were governed by anything other than § 102. *See, e.g.*, *In re Kaplan*, 789 F.2d 1574, 1579-80 (Fed. Cir. 1986) ("[T]here must be some clear evidence to establish why the variation would have been obvious which can properly qualify as 'prior art.'"); *Pfizer Inc. v. Ranbaxy Laboratories Limited*, 405 F. Supp. 2d 495, 514 (D. Del. 2005) (holding in a OTDP case that "[t]he Court is . . . not persuaded that one skilled in

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of the patents at issue, and not on comparisons with prior art as in the ordinary obviousness analysis. *See, e.g.*, *Geneva Pharm., Inv. v. GlaxoSmithKline PLC*, 349 F.3d 1373, 1377 n.1 (Fed. Cir. 2003). *Cf. Sanofi-Synthelabo v. Apotex Inc.*, 492 F.Supp.2d 353, 393 (S.D.N.Y. 2007) ("Because Apotex has failed to prove at trial that the '265 patent was obvious in light of the patent as a whole, it has also necessarily failed to prove that the '265 patent was obvious in light of the specific claims of the '596 patent."). Indeed, in an opinion issued before the *Takeda* decision, one court seemed to question whether prior art played any role at all in the OTDP analysis. *See Engineered Products Co. v. Donaldson Company*, Inc., 225 F. Supp. 2d 1069, 1118-20 (N.D. Iowa 2002).

[4] The plaintiffs assert that the *Longi* approach was effectively rejected by the *Takeda* court. (*See* D.I. 81 at 5.) The court notes, however, that while the *Takeda* court rejected the strict "date of invention" approach proposed by the PTO in its *Takeda* brief, it did not hold that the date of invention was *never* the relevant date for determining whether a reference is prior art. Rather, it held that in the earlier product/later process patent scenario, using a strict "date of invention" would not comport with the policies of the OTDP doctrine. Certainly, it did not hold that the relevant dates for prior art references in OTDP cases are governed by rules completely different than those laid out in § 102.

the art would have been led to select the necessary chemicals based on the state of the art at the time"); *Medtronic, Inc. v. AGA Medical Corp.*, No. C-07-0567, 2009 WL 1163976, at *4-5 (N.D. Cal. Apr. 28, 2009) (citing *Ortho Pharm. Corp. v. Smith*, 959 F.2d 936, 940 (Fed. Cir. 1992)) ("The [OTDP] doctrine 'preclude[s] a second patent on an invention which would have been obvious from the subject matter of the claims in the first patent, in light of the prior art.'").

Moreover, in *Geneva Pharm., Inv. v. GlaxoSmithKline PLC*, the Federal Circuit noted:

> The distinctions between obviousness under 35 U.S.C. § 103 and nonstatutory double patenting include:
> 1. The objects of comparison are very different: Obviousness compares claimed subject matter to the prior art; nonstatutory double patenting compares claims in an earlier patent to claims in a later patent or application;
> 2. Obviousness requires inquiry into a motivation to modify the prior art; nonstatutory double patenting does not;
> 3. Obviousness requires inquiry into objective criteria suggesting non-obviousness; nonstatutory double patenting does not.

349 F.3d 1373, 1377 n.1 (Fed. Cir. 2003). While the Federal Circuit did not say this list was exhaustive, it demonstrates that court's desire that counsel and lower courts be aware of the need to specifically distinguish between the obviousness and OTDP analyses where necessary. Certainly, using a different set of rules to determine the relevant dates for prior art would be a significant distinction. If the Federal Circuit intended for such a different set of rules to apply, it surely would have said so in clear terms. Other than the limited holding in *Takeda*, Eli Lilly has cited no cases in which the Federal Circuit even suggested – much less clearly stated – an intention to apply a different set of prior art rules to OTDP cases.

The court appreciates the logic in Eli Lilly's argument that the policies underlying the OTDP doctrine favor admitting all evidence up until the time of the filing date of the secondary application. In an abstract sense, all events leading up to the time that the secondary application

is filed could shed light on both the scope and meaning of the claims of the secondary application. Eli Lilly is also correct that double patenting does not become an invalidity issue until the secondary application is filed. No court has ever adopted Eli Lilly's approach, however, and the court will not set aside § 102 in OTDP cases simply because logical arguments can be made for doing so.[5] Consequently, the court determines that the prior art rules, including the dates, provided in § 102 apply in this case.

Dated: November 5, 2010

CHIEF, UNITED STATES DISTRICT JUDGE

[5] Moreover, similar arguments could be made with respect to other invalidity defenses. For example, it is not the mere conception or reduction to practice of an obvious invention that creates an obviousness problem, but rather the (later) filing of a patent application claiming that obvious invention. Moreover, absent the dates set forth in § 102, one certainly would consider references that appeared between the invention date and the filing date to be potentially relevant to whether a claimed invention is obvious in light of earlier prior art, just as Eli Lilly argues that such references are potentially relevant to whether their claimed invention is an obvious variant of earlier patents.